



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE HONORABLE BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF

Ex parte Kazuhisa MATSUDA

SUTURABLE ADHESION-PREVENTING MEMBRANE

Serial Number: 09/489,473
Filed: January 21, 2000
TC/AU: 1711
Examiner: Arden B. Sperty

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Date: September 15, 2004

Atty. Docket No. NISS-049



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Appl. No. : 09/489,473 Confirmation No. 5891
Applicant : Kazuhisa MATASUDA
Filed : January 21, 2000
TC/A.U. : 1771
Examiner : Arden B. Sperty
Dkt. No. : NISS-049
Cust. No. : 20374

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 15, 2004

Sir:

This is a reply brief to the Examiner's Answer dated July 15, 2004, in the appeal to the Board of Patent Appeals and Interferences in the patent application identified above. The arguments in the Examiner's Answer are not proper for the following reasons.

- (1) Fig. 2 of Light must Be Interpreted in View of the Disclosure of Light as a Whole

The Examiner identifies Fig. 2 of the Light reference as teaching a membrane comprising a nonwoven fabric, a film layer and a sponge layer. (Page 3, lines 1-2 of the Examiner's Answer). Fig. 2 of Light, however, cannot be considered in isolation and the

entirety of the disclosure of Light must be considered in determining what Light as a whole would have fairly suggested to one of ordinary skill in the art. *In re Langer*, 59 CCPA 1256, 465 F.2d 896, 175 USPQ 169 (1972); *In re Boe*, 53 CCPA 1079, 355 F.2d 961, 148 USPQ 507 (1966).

Light describes its invention as "a bioabsorbable ligament or tendon prosthesis in the form of a multilayered spiral roll." (Col. 2, lines 46-47). The prosthesis is described as being obtained by providing a laminate of a foraminous layer of bioabsorbable material and a bioabsorbable film; coating the laminate with a layer of an aqueous gel ...; rolling up the laminate and the gel layer into a spiral roll, followed by drying the gel to form a layer of bioabsorbable sponge." (Col. 4, lines 47-52). (Emphasis appellant's). The method for preparing the prosthesis in the working examples is limited to coating a laminate with an aqueous gel, rolling up the laminate with gel layer and flash freezing the resultant helical coil to produce the prosthesis.

There is no description of making the prosthesis by providing a laminate consisting of a nonwoven fabric, a film layer and a sponge layer as shown in Fig. 2 and rolling up the laminate. In fact there is no description of Fig. 2 other than the description

of Fig. 2 in the brief description of the drawings as illustrating "stages in the method of making the bioabsorbable prosthesis of Fig. 1" (Col. 6, lines 15-16).

Figs. 4 and 5, which are similar to Fig. 2, are described in Light as illustrating alternative laminate structures for forming the bioabsorbable prosthesis.

When its disclosure is considered as a whole, the only reasonable suggestion that emerges from Light is that Fig. 2 and Fig. 4 illustrate the different positional relationships of the different layers in the rolled-up laminate.

Appellant notes that Light cannot support anticipation of the membrane of the present invention (assuming that the membrane of Fig. 2 of Light included a non-woven fabric layer made of collagen fibers, a layer made of collagen, and a coating layer of gelatin or hyaluronic acid) because an ambiguous reference cannot support anticipation. *In re Turlay*, 49 CCPA 1288, 304 F.2d 893, 134 USPQ 355. If Fig. 2 of Light cannot support anticipation of a membrane including a non-woven fabric layer made of collagen fibers, a layer made of collagen, and a coating layer of gelatin or hyaluronic acid, it cannot logically support the obviousness of a membrane including these layers.

(2) Light Does Not Disclose a Non-woven Fabric Layer of Collagen Fibers

The Examiner in the paragraph beginning near the bottom of page 3 of the Examiner's Answer states that, with respect to the claimed process limitations, the membrane of Light is identical to or only slightly different than the membrane prepared in the present invention.

Appellant does not understand the process limitations to which the Examiner is referring. However, regardless of whether or not the claims on appeal are considered to recite product-by-process limitations, Light does not disclose or suggest a membrane which includes a non-woven fabric layer of collagen fibers as required by the claims on appeal. First, the invention of Light is not a membrane - it is a prosthesis in the form of a multilayered spiral roll. Second, the foraminous layer of the structure of Light is not a layer of collagen fibers. The foraminous layer is a layer of a synthetic, non-collagenic, bioabsorbable material. Light describes that the synthetic bioabsorbable material:

"[p]referably, ... comprises a polymer or copolymer of lactic acid or glycolic acid, oxidized regenerated cellulose, polydioxanone (PDS), a copolymer of lactic acid and ϵ -caprolactam, polyhydroxybutyric acid or a copolymer of hydroxybutyric acid and hydroxyvaleric acid. More preferably, the foraminous layer comprises one of the copolymers of lactic acid and glycolic acid sold under the Registered Trade Mark VICRYL, or the oxidized

regenerated cellulose sold under the Registered Trade Mark SURGICEL. Most preferably, the foraminous layer comprises the melt-spun polylactide or polylactide/polyglycolide copolymer described in EP-A-0241252."

(Col. 3, lines 12). None of these materials are collagenous.

The Examiner suggests in the Examiner's Answer that the foraminous layer can be composed of collagen as described for the film layer because Light teaches that the nonwoven layer and film may be composed of the same materials. This description, however, cannot be considered in isolation, but must be considered in light of the description of Light as a whole including the description in the background of the invention of Light and the above-quoted description of useful materials of the foraminous layer.

In the background of the invention Light uses the terminology "synthetic bioabsorbable polymers" to mean non-collagenic materials. Specifically, in Col. 2, lines 27-28, Light refers to the synthetic bioabsorbable polymers described in Col. 2, lines 7-26, as "synthetic, non-collagenic polymers." Thus, since Light limits the foraminous layer to non-collagenic materials, the description in Col. 4, lines 64-65, of Light that the nonwoven layer and film may be composed of the same materials would necessarily be understood by the person of ordinary skill in the art to mean that the bioabsorbable film can be made of the non-

collagenic materials disclosed for use as the fibers of the foraminous layer.

(3) The Examiner Has Misinterpreted the Arguments Concerning Lack of Proper Motivation

The Examiner on page 5 of the Examiner's Answer alleges that appellant has argued that the result of the proposed combination of Light and Silver is a prosthesis formed solely of collagen. This position is not supported and is not correct. Appellant's position is that there is no motivation to modify the foraminous layer of Light (in view of Silver) to include fibers of collagen. Appellants position is that Light, in the background section of the invention, contrasts the properties of prostheses made of collagen with those of prostheses made of synthetic bioabsorbable materials ("synthetic, non-collagenous polymers") and then describes its invention as comprising a foraminous layer made of the synthetic bioabsorbable materials. The fact that Light specifically chose synthetic bioabsorbable materials (from the two materials disclosed, collagen and the synthetic bioabsorbable materials) for the foraminous layer is an indication that a foraminous layer made of collagen was not suitable for the prosthesis of the Light invention. This suggestion leads away from the proposed combination of Light and Silver.

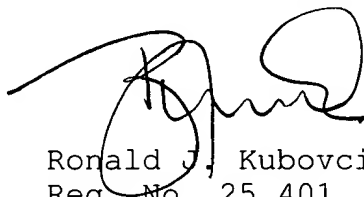
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REPLY BRIEF

For the above reasons and those explained in the appellant's appeal brief, reversal of the Examiner's final rejection of the claims is in order and is respectfully solicited.

In the event that any fees are required in connection with this paper the Commissioner is authorized to charge Deposit Account No 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK

A handwritten signature in black ink, appearing to read 'Ronald J. Kubovcik', is written over the printed name and registration number.

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